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REMARKS

Claims 1-19 remain in the application and are presented for examinations and reconsideration. Claims 5, 13, 14, 18, and 19 have been withdrawn from consideration.

ELECTION / RESTRICTION

Applicant hereby withdraws the traversal of the election of the claims of Group I. Accordingly, claims 5, 13, 14, 18, and 19 are withdrawn from further consideration.

CLAIM REJECTIONS UNDER 35 U.S.C. 112

Claims 1-4, 6-12, and 15-17, have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

In particular, claims 1 and 9 fail to distinguish the terms, "hydrophilic polymer," and "isocyanate-terminated prepolymer," according to the Examiner. Accordingly the claims 1 and 9 have been hereby amended to recite, "a hydrophilic polymer other than an isocyanate-terminated prepolymer." This will remove any unclarity and was clearly the intent of the Applicant. For example, in all of the working examples, the hydrophilic polymer differs from the isocyanate-terminated prepolymer. Also, it should be noted that the hydrophilic polymer of the present application is nowhere said to be an isocyanate-terminated prepolymer.

The Examiner has also rejected claims 1 and 9, stating that the metes and bounds of the "pharmacological additive," are indeterminate in scope. Applicant traverses this rejection for the following reasons.

According to the present application, any pharmacological additive is contemplated as having utility in the lubricant compositions. There is no reason that has been provided suggesting that a limitation on the type of pharmacological additive need or even should, be included. As far as Applicant is aware, all pharmacological additives are operative in the lubricant compositions of the invention. There is ample support for the use of the term "pharmacological additive" in the claims

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of the application. In this respect, it is stated in the originally filed application, at page 13, lines 23-29, that the pharmacological additives may be anti-microbial additives, topical anesthetics, anti-inflammatory compounds, spermicidal compounds and the like. Other types of pharmacological additives useful in the invention are anti-thrombogenic agents (specification, p.3, lines 27-28); antibiotics (specification, p.6, line 5); and organic compounds derived from plants and herbs having desirable pharmacological properties (specification, p.6, lines 28-29). The type of general and specific disclosure in the specification should suffice to indicate Applicant's intention to use any pharmacological additive. Unless there is a basis for limiting the claims, there should be no necessity for Applicant to narrow the pharmacological additives described in claims 1 and 9.

The Examiner has rejected claims 4 and 12, in use of the term, "propolyacrylate." Applicant has hereby detected the term, "propolyacrylate," from claims 4 and 12.

In review of the above, Applicant respectfully requests that the rejection of claims 1-4, 6-12, and 15-17, under 35 U.S.C. 112, second paragraph, as being indefinite, be withdrawn.

REJECTION UNDER 35 U.S.C. 103(a)
OVER U.S. 4,679,013 (Lorenz et al.) in
COMBINATION WITH U.S. 5,558,900 (Fan et al.)
And U.S. 4,467,073 (Creasy)

The Examiner has rejected claims 1-4, 6-12, and 15-17, under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,769,013 to Lorenz et al. in combination with U.S. Patent No. 5,558,900 to Fan et al. and U.S. Patent No. 4,467,073 to Creasy. Applicant respectfully traverses this rejection for the following reasons.

Accordingly to the Examiner, Lorenz et al. disclose coating compositions for medical devices, comprising a polyurethane complexed with polyvinylpyrrolidone, and a bio-affecting agent. Further, the Examiner has stated that Lorenz et al discloses, in the examples, that the coating compositions

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may include ethyl lactate. As recognized by the Examiner, however, Lorenz et al. do not expressly disclose use of the presently claimed solvents, in the coating compositions of the Lorenz et al. patent.

In an attempt to overcome the deficiencies of the Lorenz et al. disclosure, the Examiner has combined the teachings of Fan et al. and Creasy. Is is Applicant's contention that neither the teachings of Fan et al. nor Creasy, make up the deficiencies of the Lorenz et al patent for reasons as follow.

The Examiner has stated that Fan et al. disclose lubricious coatings for medical devices comprising a poly (ethylene oxide) polymer, optionally mixed with other polymers, such as polyvinylpyrrolidone, an isocyanate-terminated prepolymer, an inert organic solvent or mixture thereof that includes the presently claimed solvent and alkyl ester of a carboxylic acid. Suitable solvents are shown to include dimethylformamide, tetrhydrofuran and ethyl acetate. It is also stated that the coatings may include antimicrobial agents, anti-thrombogenic agents, and antibiotics. However, as noted by the Examiner, Fan et al. do not expressly exemplify a mixture of the inert solvent and the alkyl ester of a carboxylic acid, that is required by the claims of the present application.

Accordingly to the Examiner, Creasy discloses coating compositions for medical devices comprising polyvinylpyrrolidone, isocyanate prepolymer, an organic solvent, and a brocide. Suitable solvents include alkyl ester of a carboxylic acid, such as ethyl lactate and methylene chloride. As noted by the Examine, however, Creasy does not expressly exemplify mixtures of both the ethyl lactate, and methylene chloride, that are required by the claims of the present application.

The Examiner has concluded that the similarities of Lorenz et al., Fan et al., and Creasy, are such that one of ordinary skill in the art would have combined the teachings to obtain Applicant's presently claimed invention. Applicant disagrees with this conclusion, and contends that there is

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no motivation to combine the teachings of the references, as stated by the Examiner. Applicant's reasoning regarding lack of motivation to combine the reference follows.

Lorenz et al., as stated by the Examiner, fails to expressly disclose use of the solvents required by the claims of the present application. In addition, Lorenz et al. is restricted to using, as the material of the patent, polyvinylpyrrolidone that has been rendered insoluble in water and body fluids by being complexed with a polyurethane. This is the only material said to be useful by Lorenz et al., in preparing coatings for medical devices. In the examples of Lorenz et al., ethyl lactate is utilized to successfully produce the desired products. There is nothing in Lorenz et al. indicating a need to incorporate any of the solvents of Applicant's claimed invention, in order to successfully achieve the claimed invention of Lorenz et al. Therefore, it is not apparent to Applicant that Lorenz et al. would be requiring, or even desiring or needing, modification in accordance with the teachings of Fan et al. or Creasy, even if the teachings were appropriate.

With respect to Fan et al., the material of the invention is clearly directed to a solution of a poly (ethylene oxide) and a polyisocyanate in an inert solvent, where the weight ratio of poly (ethylene oxide) and a polyisocyanate in an inert solvent, where the weight ratio of poly (ethylene oxide) to polyisocyanate ranges from about 0.5/1.0 to about 125/1. Fan et al. state that the excellent performance of a coating for medical devices is believed to be attributable to the formation of a poly (ethylene oxide) polyurea complex through an in-situ hydrolysis of the polyisocyanate in the system. Furthermore, as described in column 16, line 44 - column 17, line 28, of Fan et al., the specified weight ratios of the poly (ethylene oxide) to polyisocyanate, is important to provide a lubricious and durable coating when wet.

In all examples of Fan et al., the material of the invention is a composite of a poly (ethylene oxide) and a polyisocyanate. As the Examiner has pointed out, Fan et al. states that, if desired, other water-soluble polymers, such as polyvinylpyrrolidone, may be added, to the system. However, as stated by Fan et al., the poly (ethylene oxide) is an essential water-soluble polymer in the coating solution. The entire content of Fan et al. is directed to lubricious coatings containing the poly

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(ethylene oxide) / polyisocyanate composites, in a specific weight ratio. No other polymer system is even mentioned, other than a statement by Fan et al., that other water-soluble polymers may be added to the poly (ethylene oxide) / polyisocyanate systems.

In light of the above, Applicant believes it is a fair representation that all the discussion in Fan et al. relating to solvents and alkyl esters of carboxylic acids that may be used, should be construed as being in connection with only poly (ethylene oxide) / polyisocyanate systems. Moreover, in all of the examples of Fan et al., where the polymer system is a poly (ethylene oxide) / polyisocyanate composite, the only solvent used is dichloroethane, optionally with toluene, which is not a solvent defined in the claims of Applicant's application.

Bearing in mind that Lorenz et al. is specifically directed to using, as a material for coatings, a polyvinylpyrrolidone complexed with a polyurethane, it is unclear that Lorenz et al. would be motivated to look to Fan et al. for any modification. Fan et al. are concerned only with poly (ethylene oxide) / polyisocyanate systems. There is no reason that the content of the Lorenz et al. and the Fan et al. patents would be similar such that one of ordinary skill in the art would consider each other if modifications involving either patent were to be made.

It is Applicant's contention that Creasy is also not similar to either Lorenz et al. or Fan et al., such that one of ordinary skill in the art would consider a modification to be made to Lorenz et al. or Fan et al. by looking to the teachings of Creasy.

Creasy is not directed to a coating composition to impart lubricity to a medical article. Rather, Creasy is related to transparent, anti-fog coating compositions.

The anti-fog liquid coating compositions of Creasy comprise a polymer such as polyvinylpyrrolidone, reacted or crosslinked with an isocyanate prepolymer to provide a reaction product, to which reaction product is chemically bound a surfactant. The resultant material, that is a surfactant bound to a reaction product of the polyvinyleyrrolidone and the isocyanate prepolymer, is

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dissolved in an organic solvent that is substantially non reactive with the solid ingredients of the surfactant containing reaction product. For purposes of emphasis, the organic solvent that is disclosed in Creasy is a solvent that will form a solution of a product resulting from reacting a surfactant with a reaction product of a polymer such as polyvinyl-pyrrolidone and an isocyanate prepolymer.

It is this product resulting from complexing or reacting a surfactant with a polyvinylpyrrolidone that has been reacted with an isocyanate prepolymer, that is indicated by Creasy to provide anti-fog liquid coating compositions, when dissolved in a suitable organic solvent. There is nothing in Creasy that indicates the coating compositions would be suitable to provide lubricity to a medical article.

Any discussion regarding solvents in Creasy must be understood to be organic solvents that will form a solution of the surfactant-containing reaction product of polyvinylpyrrolidone and isocyanate, and that are substantially non reactive with the solid ingredients. Accordingly, it is without basis for one to assume that the solvents of Creasy apply to use with any material other than the surfactant-containing materials that are used to provide coatings with improved fog resistance.

In view of the above, Applicant contends that one of ordinary skill in the art of lubricious coatings would not look to the art of anti-fog coating compositions, if a modification were to be made. Therefore, Applicant contends that one seeking to modify Lorenz et al., or even Fan et al., would not be motivated to look to Creasy for the modification. Further, the Applicant's claimed invention that requires the presence of both a certain solvent and an alkyl ester of a carboxylic acid in a coating composition is not expressly exemplified in Creasy.

In light of the foregoing, Applicant does not agree that claims 1-4, 6-12, and 15-17, are unpatentable, under 35 U.S.C. 103(a), over Lorenz et al., in combination with Fan et al. and Creasy. As pointed out, there is no reasonable basis for one of ordinary skill in the art to have combined the cited references, and thereby render obvious Applicant's claimed invention. Accordingly, Applicant

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requests the Examiner to withdraw the rejection of claims 1-4, 6-12, and 15-17, under 35 U.S.C. 103(a).

CONCLUSION

Applicant believes the application is in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the rejections of the claims, under 35 U.S.C. 112, and under 35 U.S.C. 103(a). Applicants submit that claims 1-4, 6-12, and 15-17 are patentable, and respectfully request the Examiner to pass the application to issue.

Respectfully submitted,



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